

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty. Docket: LANGE6A

In re Application of:)	Conf. No.: 2286.
Birgitte Holst LANGE et al.)	
IA No: PCT/DK04/00529)	Art Unit: 1654
IA Filed: August 6, 2004)	Examiner: J. Ha
Appln. No.: 10/567,406)	Washington, D.C.
For: USES OF SECRETAGOGUES)	October 19, 2006
LIKE GHRELIN IN CANCER CACHEXIA))	
AND FOR STIMULATING APPETITE)	

INFORMATION DISCLOSURE STATEMENT [IDS]

Honorable Commissioner for Patents
U.S. Patent and Trademark Office
Customer Service Window
Randolph Building, Mail Stop Amendment
401 Dulany Street
Alexandria, VA 22314

Sir:

This Information Disclosure Statement is submitted in accordance with 37 CFR §§1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

[X] 1. This IDS should be considered, in accordance with 37 CFR §1.97, as it is filed:

[] A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application.

[X] B. before the mailing date of a first office action on the merits or before the mailing of a first Office

action after the filing of a Request for Continued Examination under 37 CFR \$1.114; or

☐ C. after (A) and (B) above, but before final rejection or allowance, and Applicant has made the necessary certification (box "i" below) or paid the necessary fee (box "ii" below):

☐ i. Counsel certifies that, upon information and belief, each item of information listed herein either was

☐ (a) first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or

☐ (b) not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, not known to any individual designated in 37 CFR \$1.56(c) more than three months prior to the filing of this IDS.

☐ ii. Credit Card Payment Form, PTO-2038, is attached authorizing payment of the fee set forth in 37 CFR \$1.17(p), presently believed to be \$180. If the enclosed payment is incorrect, please charge any additional fees or credit any overpayment to Deposit Account No. 02-4035 of the undersigned.

☐ D. after (A), (B) and (C) above, but before payment of the issue fee: Applicant states as follows under 37 CFR \$1.97(e) for consideration of this IDS, that, upon information and belief, each item of information listed herein either was

☐ (a) first cited in a communication from a foreign patent office in a counterpart foreign

application not more than three months prior to the filing of this IDS; or

- ☐ (b) not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, not known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this IDS.

Credit Card Payment Form, PTO-2038, is attached authorizing payment of the fee set forth in 37 CFR §1.17(p), presently believed to be \$180. If the enclosed payment is incorrect, please charge any additional fees or credit any overpayment to Deposit Account No. 02-4035 of the undersigned.

☒ 2. In accordance with 37 CFR §1.98, this IDS includes a list (e.g., form BN/SB/08A/B) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. Other than U.S. patent(s) and/or published U.S. application(s), which 37 CFR §1.98(a)(2)(ii) does not require to be filed unless specifically required by the Office, a copy of each document listed is attached, except as explained below:

☐ A. Document(s) _____ is/are deemed substantially cumulative to document(s) _____, and, in accordance with 37 CFR §1.98(c), a copy of each of the former document(s) is not enclosed.

☐ B. Certain documents were previously cited by or submitted to the Office in the following prior application(s), which are relied upon under 35 U.S.C. 120:

(insert serial numbers and filing dates of prior applications)

Applicant identifies these documents by attaching hereto copies of the forms PTO-892, PTO-1449, PTO/SB/08a and/or PTO/SB/08b (or their BN form equivalents) from the files of the prior application(s) or a fresh BN/SB/08A and/or BN/SB/08B listing these documents, and request that they be considered and made

of record in accordance with 37 CFR §1.98(d). Per 37 CFR §1.98(d), copies of these documents need not be filed in this application.

[X] 3. Document AK is not in the English language. In accordance with 37 CFR §1.98(a)(3), Applicant states:

[X] An English translation of each document AK (or of the pertinent portions thereof), or a copy of an English-language abstract (or claim) is enclosed.

[] For documents _____, a corresponding English-language patent or published application is included on the accompanying Form BN/SB/08A, with a line drawn in the margin connecting the non-English-language document with its corresponding English-language document.

[] A concise explanation of the relevance of document(s) _____ is found in the attached _____ search report (see reply to Comment 68 in the preamble to the final rules; 1135 OG 13 at 20).

[] A concise explanation of the relevance of document(s) _____ is set forth as follows:

[] A concise explanation of the relevance of document(s) _____ can be found on page(s) _____ of the specification.

[] A concise explanation of the relevance of document(s) _____ can be found on the attached sheet.

[X] 4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 and 68 in the preamble to the final rules; 1135 OG 13 at 20).

[] 5. Other information being provided for the examiner's consideration follows:

In re Appln. No. 10/567,406

6. In accordance with 37 CFR §§1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in 37 CFR §1.56(b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

Respectfully submitted,

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SUBSTITUTE FOR FORM IPC/SB/08 INFORMATION DISCLOSURE STATEMENT LIST OF DOCUMENTS CITED BY APPLICANT		ATTY DOCKET NO: LANGE6A FIRST INVENTOR: Birgitte Holst LANGE FILING DATE: August 6, 2004 EXAMINER: J. Ha		SERIAL NO: 10/567,406 ART UNIT: 1654		
U.S. PATENT DOCUMENTS (include at least patentee, patent/pub number and filing/issue/pub date)						
EXAM. INITIAL	ID	DOCUMENT NUMBER	FILING, ISSUE OR PUBLICATION DATE MM-DD-YYYY	PATENTEE OR APPLICANT	Relevant Passage(s)	T
J.H./	AA	US 5,798,337	08-09-2001	Genentech Inc.		
J.H./	AB	US 2005/0014794	01-20-2005	Liu et al.		
FOREIGN PATENT DOCUMENTS (include at least document number, publication date and country)						
EXAM. INITIAL	ID	COUNTRY CODE & DOCUMENT NUMBER	PUBLICATION DATE MM-DD-YYYY	PATENTEE OR APPLICATION	Relevant Passage(s)	T
J.H./	AC	WO 01/56592 A1	08-09-2001	Novo Nordisk A/S		
	AD	EP 1 186293 A2	03-13-2002	Pfizer Products Inc.		
	AE	WO 01/92292 A2	12-06-2001	Merck & Co., Inc.		
	AF	EP 1 197 496 A1	04-17-2002	Kangawa et al		
	AG	WO 02060472	08-08-2002	Chugai Pharmaceutical Co. Ltd., et al.		Yes
	AH	WO 03/004518 A2	01-16-2003	Ardana Bioscience Limited		
	AI	WO 2004/009616 A2	01-29-2004	Societe Conseils de Recherches et D'applications Scientifiques (S.C.R.A.S.)		
	AJ	EP 1 186 293 A2	03-13-2002	Pfizer Products Inc.		
V	AK	WO 03/097083 A1	11-27-2003	Daiichi Suntory Pharma Co. Ltd., et al.		Yes
OTHER DOCUMENTS (include AUTHOR, title, name of publication, volume, pages & date of publication)						
J.H./	AL	Wren et al: "Ghrelin enhances appetite and increases food intake in humans" The Journal of Clinical Endocrinology & Metabolism, 86 (12):5992-5995				
EXAMINER				DATE CONSIDERED Oct 19, 2006		
EXAMINER: Initial if reference considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.						

* "Relevant Passages" column is optional. Put check in "T" column if English translation of entire document included. If English language abstract included, put A in this box. If ref. in English, put "E". If requirement otherwise met, put O.

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OTHER DOCUMENTS (include AUTHOR, title, name of publication, volume, pages & date of publication)			
/J.H./	AM	Nagaya et al: "Ghrelin improves left ventricular dysfunction and cardiac cachexia in heart failure"; Current opinion in Pharmacology, 2003, 3:146-151, XP-002311021	
	AN	Van den Berghe: "Growth Hormone Secretagogues in Critical Illness"; Hormone Research, 1999; 51 (suppl 3):21-28, XP-009041731	
	AO	Hayashida et al., "Ghrelin in neonatal rats: distribution in stomach and its possible role", J Endocrinology 2002 May; 173(2):239-245 - Publication date: May 2002	
	AP	Obal et al., "Sleep in mice with nonfunctional growth hormone-releasing hormone receptors", Am J Physiol Regul Integr Comp Physiol. 2003 Jan;284(1):R131-9. Epub 2002 Oct 3. Publication date: October 2002	
	AQ	Sibilia et al., "Ghrelin protects against ethanol-induced gastric ulcers in rats: studies on the mechanisms of action", Endocrinology. 2003 Jan;144(1):353-9. Publication date: 1 October 2002	
	AR	Enomoto et al., "Cardiovascular and hormonal effects of subcutaneous administration of ghrelin, a novel growth hormone-releasing peptide, in healthy humans"; Clinical Science Immediate Publication (Lond). 2003 Oct;105(4):431-5; published on 29 May 2003 as manuscript CS20030184	
	AS	Nakahara et al., "Effect of chronic treatments with ghrelin on milk secretion in lactating rats"; Biochemical and Biophysical Research Communication. 2003 Apr 11;303(3):751-5 Publication date: 4 February 2003	
	AT	Hanada et al., "Anti-cachectic effect of ghrelin in nude mice bearing human melanoma"; Biochemical Biophysical Research Communication. 2003 Feb 7;301(2):275-9 Publication date: 16 December 2002	
	AU	Torsello et al., "Ghrelin plays a minor role in the physiological control of cardiac function in the rat"; Endocrinology. 2003 May; 144(5):1787-92 Publication date: 22 January 2003	
↓	AV	Tschöp et al. "GH-Releasing Peptide-2 Increases Fat Mass in Mice Lacking NPY: Indication for a Crucial Mediating Role of Hypothalamic Agouti-Related Protein", Endocrinology. 2002; 143(2):558-568 Publication date: 15 October 2001	
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/J.H./	AW	Asakawa et al. "Ghrelin is an appetite-stimulatory signal from stomach with structural resemblance to motilin"; Gastroenterology. 2001 Feb;120(2):337-45 Publication date: February 2001		
	AX	Horvath et al. "Minireview: Ghrelin and the Regulation of Energy Balance - A Hypothalamic Perspective; Endocrinology. 2001, Vol.142, No. 10 4163-4169 Publication date: 27 July 2001		
	AY	Nagaya et al. "Elevated Circulating Level of Ghrelin in Cachexia Associated With Chronic Heart Failure Relationships Between Ghrelin and Anabolic/Catabolic Factors"; Circulation. 2001; 104:2034-2038 Publication date: 14 August 2001		
	AZ	Jeffery et al. "The potential autocrine/paracrine roles of ghrelin and its receptor in hormone-dependent cancer"; Cytokine & Growth Factor Reviews, 14, 2003, 113-122 Publication date: 2003		
	BA	Wisse et al. "Reversal of Cancer Anorexia by Blockade of Central Melanocortin Receptors in Rats" Endocrinology, Vol 142, No. 8, 3292-3301 Publication date: 16 April 2001		
	BB	Jeffery et al. "Expression and action of the growth hormone releasing peptide ghrelin and its receptor in prostate cancer cell lines"; Journal of Endocrinology, 2002 Mar;172 (3):R7-11 Publication date: 8 February 2002		
	BC	Volante et al. "Expression of Ghrelin and of the GH Secretagogue Receptor by Pancreatic Islet Cells and Related Endocrine Tumors"; The Journal of Clinical Endocrinology & Metabolism, Vol 87, No. 3, 1300-1308, Publication date: 13 November 2001		
	BD	Hosoda et al., "Ghrelin and the Regulation of Food Intake and Energy Balance", Molecular Interventions 2:494-503 (2002)		
	BE	Tolle et al. "Uladian rhythmicity of ghrelin secretion in relation with GH, feeding behavior, and sleep-wake patterns in rats"; Endocrinology, 2002 Apr;143 (4):1353-61 Publication date: 4 December 2001		
	BF	Tschöp, M., et al. "Circulating Ghrelin Levels Are Decreased in Human Obesity"; Diabetes, Vol. 50, April 2001, 707-709		
✓	BG	Tschöp, M., et al. Ghrelin induces adiposity in rodents"; Nature, Vol. 407, 19 October 2000, 908-913.		
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